K002253

JUL - 3 2001

510(k) SUMMARY
AS REQUIRED BY SECTION 807.92(C)

Identification: DrugFree@Home™ THC/COC Test Kit

Description: One step, colloidal gold based chromatographic immunoassay for the rapid, qualitative detection of Cannabinoids (THC) and Cocaine in urine.

Name of Manufacturer:

Forefront Diagnostics, Inc.
23561 Ridge Route Dr. Suite D
Laguna Hills, CA 92653

Intended Use: The Forefront Diagnostics DrugFree@Home™ THC/COC Test kit is an *in vitro* screen test for the rapid detection of THC and Cocaine in urine. The cutoff concentration is 50ng/ml and 300ng/ml respectively. The test kit is used to obtain a visual, qualitative result and is intended for over the counter sale to laypersons.

Technology: The Forefront Diagnostics DrugFree@Home™ THC/COC Test kit, like multi-drug test kits from other manufacturers such as Roche, Applied Biotech, etc. quantitatively measures the presence of target drugs or their metabolites by visual color sandwich one step immunoassay technology. All of these products are based on the same immunochemical principal of recognition and formation of specific antibody / target drug / antibody / complexes.

Performance: The product performance characteristics of the DrugFree@Home™ THC/COC Test kit was evaluated in a blind-labeled spiked control study, a blind-labeled clinical specimen correlation study, and in a consumer accuracy study. The results of these studies demonstrate the DrugFree@Home™ Test kit to be substantially equivalent to other commercially available test kits for the qualitative detection of target drugs in urine. Correlation studies, using clinical specimens, produced a 92% correlation when compared to the predicate kit and GC/MS methodology. Clinical site studies were performed at Forefront Diagnostics, Inc and at three independent laboratories. The results of this study demonstrate that the DrugFree@Home™ Test kit can be performed by professional and laboratory personnel to obtain a visual, qualitative, rapid detection of drugs of abuse in its metabolites with an accuracy of 98.3%. The consumer accuracy study was performed by comparing consumer findings against GC/MS reported values. The study resulted in 96.5% agreement between consumer findings and GC/MS reported values.

Conclusion: For the reasons mentioned above, it may be concluded that the DrugFree@Home Test kit is substantially equivalent to the devices presently distributed commercially and is safe for the lay user.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL - 3 2001

Mr. Feng Yu Lee
Vice President Quality System
Forefront Diagnostics, Inc.
23561 Ridge Route Drive, Suite D
Laguna Hills, CA 92653

Re: 510(k) Number: K002253
Trade/Device Name: DrugFree@Home THC/COC Test Kit
Regulation Number: 862.3250, 862.3870
Regulatory Class: II
Product Code: DIO, LDJ
Dated: April 26, 2001
Received: April 30, 2001

Dear Mr. Lee:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K002253

Device Name: DrugFree@Home THC/COC Test Kit

Indications For Use:

The Forefront Diagnostics DrugFree@Home THC/COC Test Kit is an *in vitro* home screen test for the rapid detection of 11-nor-Δ^9-Tetrahydrocannabinol-9-carboxylic acid (THC) and cocaine and its metabolite, benzoylecgonine in human urine at above the following concentrations:

THC	**11-nor-Δ^9-THC-9-COOH**	**50 ng/ml**
COC	**Benzoylecgonine**	**300 ng/ml**

It provides a preliminary analytical result, and if necessary, a pre-paid confirmation test (GC/MS) is included. The test kit is used to obtain a visual, qualitative result and is intended for over the counter sale to the home user.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K002253

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)